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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/510,268	02/22/2000	H. Lee Sweeney	9596-61U1-(209596.0336)	1583

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EXAMINER

FALK, ANNE MARIE

ART UNIT PAPER NUMBER

1632

DATE MAILED: 04/08/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/510,268

Applicant(s)

SWEENEY ET AL.

Examiner

Anne-Marie Falk, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 30 May 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) 19-22 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 7-12, 16, 18 and 23 is/are allowed.
- 6) ☒ Claim(s) 1-6, 13-15, 17 and 24 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 February 2000 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

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### DETAILED ACTION

The amendment filed January 23, 2002 (Paper No. 12) has been entered. Claims 1 and 7-9 have been amended. Claim 24 has been newly added.

The amendment filed May 28, 2002 (Paper No. 14) has been entered.

Claims 19-22 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b) as being drawn to a non-elected invention. Election was made **without** traverse in Paper No. 7.

The following rejections are reiterated or newly applied and constitute the complete set of rejections being applied to the instant application. Rejections and objections not reiterated from the previous office action are hereby withdrawn.

Claims 1-18, 23, and 24 are examined herein.

### *Drawings*

The drawings are objected to for the reasons set forth on the Notice of Draftsperson's Patent Drawing Review (PTO-948) mailed 5/9/01 as part of Paper No. 6. New drawings must be submitted in response to this Office Action. Applicant may not request that any objection to the drawings be held in abeyance. See 37 CFR 1.85(a).

### INFORMATION ON HOW TO EFFECT DRAWING CHANGES

#### 1. **Correction of Informalities -- 37 CFR 1.85**

New corrected drawings must be filed with the changes incorporated therein. Identifying indicia, if provided, should include the title of the invention, inventor's name, and application number, or docket number (if any) if an application number has not been assigned to the application. If this information is provided, it must be placed on the front of each sheet and centered within the top margin. If corrected drawings are required in a Notice of Allowability (PTOL-37), the new drawings **MUST** be filed within the **THREE MONTH** shortened statutory period set for reply in the "Notice of Allowability." Extensions of time may **NOT** be obtained under the provisions of 37 CFR 1.136 for filing the corrected drawings after the mailing of a Notice of Allowability. The

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drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftsperson.

**2. Corrections other than Informalities Noted by Draftsperson on form PTO-948.**

All changes to the drawings, other than informalities noted by the Draftsperson, **MUST** be made in the same manner as above except that, normally, a highlighted (preferably red ink) sketch of the changes to be incorporated into the new drawings **MUST** be approved by the examiner before the application will be allowed. No changes will be permitted to be made, other than correction of informalities, unless the examiner has approved the proposed changes.

**Timing of Corrections**

Applicant is required to submit acceptable corrected drawings within the time period set in the Office action. See 37 CFR 1.185(a). Failure to take corrective action within the set (or extended) period will result in **ABANDONMENT** of the application.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 13-15 and 17 stand rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 13 is indefinite in its recitation of "said isolated nucleic acid of claim 12" because the phrase lacks antecedent basis." Claims 14, 15, and 17 are indefinite in so far as they depend from Claim 13. Use of the phrase "the isolated nucleic acid of claim 12" is suggested.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-4 and 24 are rejected under 35 U.S.C. 102(e) as being anticipated by US 2003/0018984

A1 (Coleman et al.; published Jan. 23, 2003; priority to Dec. 2, 1996).

The claims are directed to a method of increasing vertebrate muscle mass and muscle strength by administering a muscle enhancing dose of an isolated nucleic acid encoding insulin-like growth factor I (IGF-1) intramuscularly into a vertebrate, wherein said isolated nucleic acid is expressed in muscle cells, thereby increasing said muscle mass and said muscle strength in said vertebrate.

Coleman et al. disclose that intramuscular injection of a plasmid vector encoding human IGF-1 resulted in increased muscle mass in rats (paragraphs 0230 to 0233) and mice (paragraphs 0307 to 0311 and Table VI). The reference further discloses that this method is also applicable to humans and is particularly useful for the treatment of muscle atrophy due to age (paragraphs 0321 to 0324). Coleman et al. give explicit direction to use the vector encoding human IGF-1 in humans (paragraph 0324), thereby teaching the method of the invention of Claim 4 (limited to using an IGF-1 of the same species as the vertebrate being treated).

Thus, the claimed invention is disclosed in the prior art.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary.

Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 5 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 2003/0018984 A1 (Coleman et al.; published Jan. 23, 2003; priority to Dec. 2, 1996) and Xiao et al. (1996, J. Virol. 70(11): 8098-8108).

The claim is directed to a method of increasing vertebrate muscle mass and muscle strength by administering a muscle enhancing dose of an isolated nucleic acid encoding insulin-like growth factor I (IGF-I) intramuscularly into a vertebrate, wherein said isolated nucleic acid is expressed in muscle cells, thereby increasing said muscle mass and said muscle strength in said vertebrate, wherein said isolated nucleic acid is contained within a virus vector.

Coleman et al. disclose that intramuscular injection of a plasmid vector encoding human IGF-1 resulted in increased muscle mass in rats (paragraphs 0230 to 0233) and mice (paragraphs 0307 to 0311 and Table VI). The reference further discloses that this method is also applicable to humans and is particularly useful for the treatment of muscle atrophy due to age (paragraphs 0321 to 0324). Coleman et al. does not disclose the use of viral vectors encoding IGF-1.

Xiao et al. disclose the administration of a viral vector to muscle for the purpose of gene transfer and producing an exogenous protein in the muscle. Gene expression persisted for more than 1.5 years (abstract).

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Since Xiao et al. demonstrated that an adeno-associated virus vector could be used to achieve long-term expression of an exogenous gene in muscle tissue, one of skill in the art would have been motivated to make an adeno-associated virus vector comprising an IGF-1 gene for administration to animal muscle to achieve long-term expression of the gene and thereby prolong the effect to maintain increased muscle mass and strength. The skilled artisan would have anticipated a reasonable expectation of success for using an AAV vector encoding IGF-1 because the in vivo effect of IGF-1 was already known and the use of AAV vector to achieve long-term expression of an exogenous gene in muscle was likewise already known. Therefore it would have been obvious to one of skill in the art at the time of the invention to have used an AAV vector encoding IGF-1 for intramuscular administration to achieve increased muscle mass and strength.

Therefore, the claimed invention would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention.

### *Conclusion*

Claims 7-12, 16, 18 and 23 are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne-Marie Falk whose telephone number is (703) 306-9155. The examiner can normally be reached Monday through Thursday and alternate Fridays from 10:00 AM to 7:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached on (703) 305-4051. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the patent analyst, William Phillips, whose telephone number is (703) 305-3482.

Anne-Marie Falk, Ph.D.

*Anne-Marie Falk*  
ANNE-MARIE FALK, PH.D.  
PRIMARY EXAMINER